k080314

K-35

510 (k) Summary of Safety and Effectiveness

Date Summary Prepared:	February 1, 2008
Submitter Information:	Spinal USA 644 Lakeland East Drive Suite A Flowood, MS 39232
Contact Name:	Jeffrey Johnson
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E-mail:	jeff@spinalusa.com
Device Trade Name:	Spinal USA Intervertebral Body Fusion Device
Common Name:	Intervertebral Body Fusion Device
Regulatory Number:	888.3080, 888.3060
Classification:	Class II
Product Code:	MAX, ODP, KWQ

INTENDED USE:

The Spinal USA Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The Spinal USA Interbody Fusion Device ACIF System is intended for use in the cervical spine, from C3 to T1, for the treatment of cervical disc disease defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The cervical device is to be used with supplemental fixation and autogenous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

The Spinal USA Interbody Fusion Device ALIF, PLIF, TLIF System are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with supplemental fixation and autogenuos bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

The Spinal USA Interbody Fusion Device RPIF System is intended to be used only in anterior procedures in which an ALIF device of the same height is implanted. The RPIF device is not meant for stand alone use.

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DEVICE DESCRIPTION:

The Spinal USA Interbody Fusion Device consists of implants with various widths, heights, lengths and bone screws to accommodate individual patient anatomy and graft material size. All components are manufactured from Ti-6Al-4V titanium alloy (ASTM F136). The products are supplied clean and "NON-STERILE".

EQUIVALENT DEVICE:

Documentation was provided which demonstrated the Spinal USA Interbody Fusion Device to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spinal USA
% Mr. Jeffrey Johnson
644 Lakeland East Drive
Suite A
Flowood, MS 39232

MAY 13 2008

Re: K080314
Trade/Device Name: Spinal USA Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Spinal intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, ODP, KWQ
Dated: May 7, 2008
Received: May 8, 2008

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080314

Device Name: Spinal USA Interbody Fusion Device

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkn

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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